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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,663	09/26/2001	Brenda Rojas	1194.003US1	3050
7590	01/30/2004		EXAMINER	
Kathy Smith Dias, Esq. Heslin Rothenberg Farley & Mesiti P.C. 5 Columbia Circle Albany, NY 12203			HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/965,663	ROJAS ET AL.	
	Examin r Georgia L. Helmer	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-25 are pending and are examined in the instant action.
2. The preliminary amendment dated 27 December 2001 has been entered.

### ***Information Disclosure Statement***

3. Applicant's IDS, form 1449, filed 15 February 2002, is acknowledged and a signed copy is included with the Office Action.

### ***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on Application Number 2,267,014 on 26 March 1999. It is noted, however, that applicant has not filed a certified copy of the priority application as required by 35 U.S.C. 119(b). Therefore, Applicant has benefit of PCT/CA00/00306 filed 24 March 2000.

### ***Claim Rejections - 35 USC § 112 second paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10 and 17, and all claims dependent thereon,

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- are incomplete method claims because the final step of the method does not produce the desired product, namely a whole plant.
- “gene” is unclear because a “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant’s intention, the language “a DNA of interest” is suggested. Or Applicant may recite the various components of the “gene” desired. All recitations of “gene” are also rejected.

In claim 2(i), the word “the” needs to be inserted between the words “in” and “absence” for clarity.

In claims 3, 12, and 19, what does a “regular” binary vector mean? Is this a non-supervirulent binary vector?

In claims 4, 14 and 21, what does “callused coleoptile node” mean in terms of being an explant tissue?

In claims 8, 23-25 and all other recitations, “about” is unclear, because the metes and bounds of “about” are not apparent.

In claim 13, the recitation of “fresh media of step (v)” of claim 10 lacks antecedent basis because step (v) does not recite “fresh media”.

Correction/clarification is required.

***Claim Rejections - 35 USC § 112 Enablement***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The breadth of the claims: Applicant claims are drawn to a method of for the transformation of any monocot plant comprising (i) exposing any explant tissue of the plant to any Agrobacterium strain under vacuum in the presence of any phenolic compound, said Agrobacterium comprising a heterologous gene within a vector, (ii) removing said Agrobacterium from the explant tissue, (iii) adding an antibiotic against Agrobacterium, and (iv) selecting explant tissue for occurrence of the heterologous gene of interest; also further comprising (2i) maintaining the explant tissue on media in the absence of a selection agent to produce differentiated calli, (2ii) transferring the differentiated calli to media containing a selection agent, and (2iii) obtaining callus that grow in the presence of the selection agent, where in the Agrobacterium is a regular binary or a supervirulent binary vector, where the explant tissue is unspecified or is

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callused coleoptile node or zygotic embryo, where the phenolic compound is unspecified or is acetosyringone, where the tissues are exposed under vacuum for 10-15 minutes.

The state of the art, the predictability of the art, and Guidance provided: Plant transformation procedures employing plant tissue culture protocols are unpredictable. "Transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one." (Hansen et. al., 1999, Trends in plant Science, vol 4, pages 226-231, see page 230).

Agrobacterium-mediated transformation of monocots is particularly unpredictable. Early attempts largely failed, due to failure to identify transformation-competent and regenerable cells (see, e.g., Potrykus, Gene Transfer to Cereals: An Assessment, 1990, Biotechnology, 8(6): 535-542 p. 538, column 2, 3<sup>rd</sup> full ¶). Woven when success is observed, the transformation appear to be transient only (see, e.g., Narasimhulu et. al., 1996, The Plant Cell, Early transcription of Agrobacterium T-DNA genes in tobacco and maize, vol. 8, p. 874, column 2, top ¶; p. 873, column 2, first full ¶).

Applicant claims all monocots, including the taxonomically divergent species palm, orchid, iris, asparagus, onion and corn, and all explants, including leaves, roots, stems, hypocotyls, flowers and seed pods. Applicant teaches (specification, p. 12-22)

the transformation of Creeping bentgrass (p. 12), Perennial ryegrass (p. 16), cereal species from the same single family, from embryogenic calli and from embryos (p. 22).

Applicant teaches detailed steps, time durations, temperatures, light conditions, concentrations of reagents, preculture and culture conditions for the various explants. However, the claimed invention lacks most details. The lack of duration terms for "exposing", "vacuum", and "maintaining" points to the lack of criticality of these parameters. Since no duration time is claimed, the time can be anytime from very small to very large. Applicant lacks any teaching of vacuum pressure; vacuum treatment is known to be deleterious to plant tissue because water is removed from plant cells and tissue in the process, and cell structure can be compromised.

While the specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable*, and must be recited in the claims.

Applicant claims all monocots, including the taxonomically divergent species palm, orchid, iris, asparagus, onion and corn, and all explants, including leaves, roots, stems, hypocotyls, flowers and seed pods. Applicant teaches Creeping bentgrass (p. 12), and Perennial ryegrass (p. 16), species from the same single family, from embryogenic calli and from embryos (p. 22). The state of the art is that "plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one." (Hansen et. al., 1999, Trends in plant Science, vol 4, pages 226-231, see page 230.

Therefore it is unpredictable that transformation protocols and methods which work for Creeping bentgrass and Perennial ryegrass would function as desired for a broad genus of unrelated monocots other than Creeping bentgrass and Perennial ryegrass. Similarly, given the well-known recalcitrance of monocots to regeneration, and the requirement for specific explant types, especially embryos or embryogenic callus (see, e.g., Vasil, I, Process in the Regeneration and Genetic Manipulation of Cereal Crops, 1988, Biotechnology, pages 397-402, p. 399, column 2, bottom ¶ ; page 399, column 1 and column 2, top ¶), it is unpredictable whether other explant types would work.

Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Applicant claims all phenolic inducers, but recites only acetosyringone .

Acetosyringone is not representative of all phenolic compounds. Acetosyringone is a very special compound isolated from wounded plants cells and known to activate T-DNA transfer from Agrobacterium (Stachel, et. al., Identification of the signal molecules produced by wounded plant cells that activate T-DNA transfer in Agrobacterium tumefaciens, Nature vol. 318: 624-629, 1985). A host of phenolic compounds are known in the art, and other than acetosyringone, no guidance is given for which phenolic compounds would function to induce the Agrobacterium vir pathway. Guidance is not given as to the qualities of acetosyringone, which allow it to function as desired. It is unpredictable that any phenolic compound would function as desired. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a

virtually ad infinitum of possibilities other than by random trial and error, which is an invitation to experiment and does not fully enable the invention as commensurate in scope with the claims.

In view of the breadth of the claims (a method of transforming any monocot, any explant, any phenolic, any calli, and any vacuum conditions ), the nature of the invention, the unpredictability of the art, the lack the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1-3, 7, 8, are rejected under 35 U.S.C. 102(e) as being anticipated by Dong et. al., US 6,037,522, issued 14 March 2000.

Dong teaches a method for the transformation of rice comprising exposing explant tissue (column 7, lines 57-65) to Agrobacterium containing a binary vector (column 5, lines 1-8; column 8, lines 1-26, column 10, lines 8-16) under vacuum (column 8, lines 1-26) in the presence of acetosyringone (column 10, lines 40-41), removing Agrobacterium and adding antibiotics against Agrobacterium (column 10, lines 45-46), selecting explant tissue (column 11, lines 48-60).

Accordingly Dong anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-3, 7,8, 9-10, 12-13, 16-17, 19-20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et. al., US 6,037,522, issued 14 March 2000.

The teachings of Dong are discussed above. Dong et. al. teach antibiotics against Agrobacterium (column 10, lines 45-46). The choice of claforan is mere optimization of process parameters and an obvious design choice. The teachings of

Dong are discussed above. Dong et. al. teach antibiotics against Agrobacterium (column 10, lines 45-46). The choice of claforan is mere optimization of process parameters and an obvious design choice. Dong et al teach incubation in the dark (column 10, lines 49-51), subsequent dark incubation steps would have also been optimization of process parameters.

13. Claims 1-3, 6-13, 16-20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong, as discussed above, and further in view of Hiei et. al., US 5,591,616 issued 7 January 1997.

Hiei et. al. teach a super binary vector ( ). The choice of a superbinary vector is mere optimization of process parameters and an obvious design choice.

**Remarks**

14. No claims are allowed. Claims 4-5, 14-15 and 21-22 are deemed free of the prior art, given the failure of the prior art to teach or reasonably support these particular explants in Agrobacterium mediated monocot transformation.

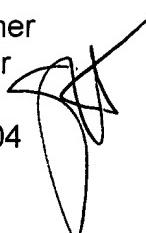
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
January 24, 2004



*Amy Nelson* for  
David Fox

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